



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/580,635

04/11/2007

Ira H. Pastan

015280-500100US

4374

45115

7590

06/09/2009

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO, CA 94111

EXAMINER

DAHLE, CHUN WU

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,635	Applicant(s) PASTAN ET AL.	
	Examiner CHUN DAHLE	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-63 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9 and 14-16 drawn to a mutated *Pseudomonas* exotoxin A (PE) and a method of inhibiting the growth of a cell bearing a target molecule by contacting said cell with a chimeric molecule comprising a mutated PE .

Group II, claims 10-13, drawn to an isolated nucleic acid encoding a mutated PE.

Group III. claims 17-42 and 61-63, drawn to an anti-CD22 antibody and a kit thereof.

Group IV. claims 43-49, drawn to a nucleic acid encoding an anti-CD22 antibody and a expression vector.

Group V. claims 50-57, drawn to a method of inhibiting the growth of cells expressing CD22 by using the anti-CD22 antibody.

Group VI. claims 58-60, drawn to a method for detecting the presence of CD22 cancer cell in a biological sample by using anti-CD22 antibody.

Art Unit: 1644

4. Unity of invention may encompass a novel product, a process of making and a process of using product. In the instant case the method of inhibiting the growth of a cell by using chimeric molecule comprising a mutated PE (encompassing claims 14-16) constitutes the first recited process of using.

The different composition of Groups I-IV do not have a common core structure or function because there is no 1:1 correlation between DNA and protein or PE and anti-CD22 antibody. (see PCT Rule 13.2 and example 17 of Annex B) in MPEP.

Species Election

5. The application contains claims directed to the following patentably distinct species of the claimed Inventions VI and V: wherein disease is:

Applicant is further required to elect one specific anti-CD22 antibody and to provide the following information with respect to the elected antibody:

- A) specific heavy chain CDR1 sequence,
- B) specific heavy chain CDR2 sequence,
- C) specific heavy chain CDR3 sequence,
- D) specific light chain CDR1 sequence,
- E) specific light chain CDR2 sequence,
- F) specific light chain CDR3 sequence,
- G) specific VH sequence, AND
- H) specific VL sequence.

These species of anti-CD22 antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site.

Art Unit: 1644

6. Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/580,635

Page 5

Art Unit: 1644

/Chun Dahle/

Examiner, Art Unit 1644